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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,678	07/12/2005	Bradley S Galer	448-70 PCT US	5133
28349 7590 03/03/2010 DILWORTH & BARRESE, LLP 1000 WOODBURY ROAD SUITE 405 WOODBURY, NY 11797				
EXAMINER				
LEWIS, AMY A				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
03/03/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,678

Applicant(s)

GALER ET AL.

Examiner

Amy A. Lewis

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.5, 6.11-17, 32-37 and 42-57 is/are pending in the application.
- 4a) Of the above claim(s) 5, 13-15, 32-37 and 42-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.6, 11, 12, 16, 17 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 10/02/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 11, 12, 16, and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5767130 (Olney et al.) in view of U.S. Patent No. 6284794 (Olesen et al.). This rejection is moot regarding cancelled claims 2-4. This rejection is maintained over claims 1, 6, 11, 12, 16 and 17, and now also applied to new claim 57, for the reasons of record and further below.

Response to Applicant's Arguments:

Applicants argue that the teachings of Olney et al and Olesen et al. set forth in the office action of 4/2/2009 is "picking and choosing" ingredients and is based on "hindsight reasoning", and is thus impermissible (see Remarks p. 15). Applicant argues that GABA agonists are listed

among many “safener agents” in the Olney reference and would not direct a skilled artisan to GABA analogs. (See Remarks p. 11-12). Applicant then states that Olesen does not correct the deficiency of Olney because gabapentin is “but one of many, many different compounds listed in this 96-column patent” (Remarks p. 13).

MPEP 2141.02 states that references are to be considered in their entirety. In response, the reference does not specifically teach away from using the claimed combination of gabapentin and dextromethorphan (a GABA agonist and an NMDA antagonist); “the prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004), cited at MPEP 2145.

References are used for all that they teach and are not limited to use of only preferred embodiments or Examples. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Regarding the Olney reference, the teaching that GABA agonists provide protection against NMDA antagonist neurotoxicity (cited previously; col. 9, lines 5-55), does not mention them among "many different compounds", but makes a significant discussion of the GABA agonist activity in 2 of four sections. The discussion of diazepam and barbiturates is within the context of GABA agonist activity, not as an alternative to a GABA agonist. Thus, one of skill in the art would be directed to the use of GABA agonists as "safening agents". And as stated in the previous office action, Olesen et al. teaches that gabapentin is a GABA receptor agonist and is useful in the treatment of tension headache (col. 43, line 55- col. 44, line 8).

Additionally, and as already set forth in the rejection, both references teach the effectiveness of dextromethorphan (the elected NMDA antagonist) for treatment of various CNS disorders. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition comprising both gabapentin (a GABA agonist) and dextromethorphan (an NMDA antagonist). One would have been motivated by the desire to gain the positive treatment effects of the NMDA antagonist while ameliorating its toxic side with the "safening agent" GABA agonist, as taught by Olney et al.

Thus, one would also have been motivated to combine the two agents in a single composition, having been taught that both are useful in the treatment of tension headache. MPEP § 2144.06 states the following: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d

846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, motivation is derived from the teachings in the art and the rejection is proper.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614